K092803 #1/1

Summary of Safety and Effectiveness

DEC 2 3 2009

Submitter: Dave Lamb
Cardo Medical Corporation
10 Clifton Blvd., Suite B1
Clifton, NJ 07011

Date Prepared: November 18, 2009

Device: Cardo Medical Align 360® Medialized Patella Component

Classification: 87KRR – Knee joint patellofemoral polymer/metal semi-constrained cemented, 21CFR 880.3540, Class II; and 87JWH Prosthesis, knee, patellofemorotibial, semi-constrained cemented polymer/metal/polymer, 21 CFR 888.3560, Class II.

Predicate Device: Cardo Medical Dome Patella – K073120 (used with patellofemoral joint), Cardo Medical Dome Patella - K081127 (used with Total Knee System), and Scorpio Knee System – K962152 and K972967.

Device Description: The Cardo Medical Align 360 Medialized patella is manufactured from UHMWPE with pegs on the non-articulating surface. The surgeon uses the components to resurface the patella during either a patella-femoral replacement or a total knee replacement. The device is designed for cemented fixation only.

Intended Use: The Cardo Medical Align 360® Medialized Patella Component is intended for cemented use in resurfacing the patella during patellofemoral disease or during total knee replacement. Patient's with patellofemoral disease may have Degenerative arthritis in the distal femur and patella; a history of patellar dislocation or fracture; or failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain deformity or dysfunction persists; whereas patients obtaining a total knee arthroplasty may have painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis; post-traumatic loss of knee joint configuration and function; moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability; or revisions of previous unsuccessful knee replacement or other procedure. Additional indications for posteriorly stabilized components include ligamentous instability requiring implant bearing surfaces with increased constraint; or absent or non-functioning posterior cruciate ligament.

Comparison to Predicates:
The Cardo Medical Align 360® Medialized Patella components are manufactured from UHMWPE have the same articulating surface as the current dome patella. The only difference is the additional material around the edge of the dome. Therefore, the devices are equivalent to the current Cardo Medical Dome Patella. In addition the Stryker, Scorpio Knee System has an oval patella component, which is a similar shape to the Cardo Medical Medialized Patella proposed in this submission.

Cardo Medical has determined that any differences in the proposed device will not impact the safety or effectiveness of the Align 360® Medialized patella components for their intended use. Testing has shown that the proposed device meets the requirements of the current FDA Guidance Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.

Synopsis of Test Methods and Results:
Tests were performed on the Align 360® Medialized patellae system to ensure the proposed device is equivalent to the predicate device for all testing performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 23 2009

Cardo Medical Corporation
% Mr. David Lamb
10 Clifton Boulevard, Suite B1
Clifton, New Jersey 07011

Re: K092803
Trade/Device Name: Cardo Medical Align 360® Medialized Patella
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, KRR
Dated: December 7, 2009
Received: December 14, 2009

Dear Mr. Lamb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K092803

Device Name: Cardo Medical Align 360® Medialized Patella

Indications for Use:

When used with the Patello-femoral System:
The Cardo Medical Patellofemoral System patella components are for use in patellofemoral knee arthroplasty in patients with:

- Degenerative arthritis in the distal femur and patella;
- A history of patellar dislocation or fracture;
- Failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain deformity or dysfunction persists.

When used with the Total Knee System:
The Cardo Medical Total Knee System patella components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorly stabilized components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

The patella components are single use only and intended for implantation with bone cement.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092803